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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,172	04/02/2004	Donald P. Bushby	Plantar Fasciitis	3082

7590 06/25/2009

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EXAMINER	
PATEL, TARLA R	
ART UNIT	PAPER NUMBER
3772	
MAIL DATE	DELIVERY MODE
06/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,172	BUSHBY, DONALD P.	
	Examiner	Art Unit	
	TARLA R. PATEL	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/3/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 44, 55, 62, 66 and 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess (6,640,465) in view of Holden (2004/0006814).

Burgess discloses an orthotic plantar fascia device for providing support to and reducing stress on, the plantar fascia of a human foot. The device comprises a thin, flexible and conformable lining; with respect to the limitation of "stretch resistant" Burgess' device (110) is both flexible and conformable to the foot. The device further includes an adhesive layer (120) on the sole engaging surface for adhering the device directly to the outer skin tissue on the sole of the foot (column 2 lines 62-67) and a protective cover (150) removably disposed over adhesive layer, that when removed, exposes the adhesive layer (column 4 lines 50-55). Also, Burgess discloses the liner will remain on the foot to allow mobility while still having increased adhesion as a greater effective contact surface area is provided (abstract). Applicant sets forth in the disclosure of the invention that the stretch resistant device" is a sufficiently flexible article with adhesive lining and that adhesive on the sole of the linings when the lining is on the surface of the foot imparts at least some restriction to extension and stretching of the tissue. The liner of Burgess when applied to the sole of the foot is applied with an adhesive and will

provide a prevention and stretch of the tissue, therefore, Burgess's liner is equivalent to the claimed support's "stretch resistant" property, since there are no other distinguish structures is required to be stretch less, the device of Burgess meets this claimed limitation. The device has a sole engaging surface (see figure 2), sized and shaped to engage the outer skin tissue on the sole of the foot (column 2 lines 38-40) and extend along the plantar fascia region of the foot from about the ball of the foot to the heel of the foot for providing support to the plantar fascia region of the foot (see fig 2).

Burgess does not disclose that the foot protector can be formed into different sizes or cuts to fit by the wearer. However, Holden teaches a protective attachment that removably attaches to the bottom of the foot (abstract) that is easily trimmed to fit the size and shape of the body part [0003]. At the time of the invention was made, it would have been obvious design choice to one having ordinary skill in the art to form the device of Burgess into different sizes or cuts to fit by the wearer, as taught by Holden to fit various size of feet and to cover whole or partial as user desire.

With respect to claim limitations to a method for reducing stress on the plantar fascia of a human foot comprising the steps of providing a thin flexible device of uniform thickness having sole engaging surface and adhering sole engaging surface to the outer skin tissue on the sole of the foot to extend from the heel of the foot to at least the mid portion of the foot to provide support to the plantar fascia region, since Burgess discloses an equivalent structure shown to be “stretch-resistant device” as explained above, the Burgess device meets the claim limitation.

3. Claims 48-54 and 56-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess and Holden in view of Domenico (3,584,622).

Burgess substantially discloses an orthotic plantar fascia device for providing support to and reducing stress on, the plantar fascia of a human foot. The device comprises a thin, flexible and conformable lining; with respect to the limitation of “stretch resistant” Burgess’ device (110) is both flexible and conformable to the foot. The device further includes an adhesive layer (120) on the sole engaging surface for adhering the device directly to the outer skin tissue on the sole of the foot (column 2 lines 62-67) and a protective cover (150) removably disposed over adhesive layer, that when removed, exposes the adhesive layer (column 4 lines 50-55). Also, Burgess discloses the liner will remain on the foot to allow mobility while still having increased adhesion as a greater effective contact surface area is provided (abstract). Applicant sets forth in the disclosure of the invention that the stretch resistant device” is a sufficiently flexible article with adhesive lining and that adhesive on the sole of the linings when the lining is on the surface of the foot imparts at least some restriction to extension and stretching of the tissue. The liner of Burgess when applied to the sole of the foot is applied with an adhesive and will provide a prevention and stretch of the tissue, therefore, Burgess's liner is equivalent to the claimed support's "stretch resistant" property, since there are no other distinguish structures is required to be stretch less, the device of Burgess meets this claimed limitation. The device has a sole engaging surface (see figure 2), sized and shaped to engage the outer skin tissue on the sole of the foot (column 2 lines 38-40) and extend along the plantar fascia region of the foot from about the ball of the

foot to the heel of the foot for providing support to the plantar fascia region of the foot (see fig 2).

However, Burgess and Holden does not discloses thin flexible straps extending laterally outward from opposite sides to at least partially encircle the talus, the navicular, the cuneiform and the cuboid region of the foot, an arch strap and a heel strap, wherein the straps can be adhered to the foot by an adhesive for securing the straps around the portions of the foot as required by claims 48,51,53,56,57,58,59,60, and 61 and With respect to claims 50,52 and 54, further, Burgess does not discloses the straps are integrally formed with device (see fig 1).

However, Domenico teaches a support device for prevention of ankle injuries comprising thin flexible straps extending laterally outward from opposite sides to at least partially encircle the talus, the navicular, the cuneiform and the cuboid region of the foot, an arch strap and a heel strap (26 as shown see figs 2 and 4), wherein the straps can be adhered to the foot by an adhesive (column 2 lines 51-54) for securing the straps around the portions of the foot (see figure 2 and 4 and column 2 lines 51-54) as required by claims 48,51,53,56,57,58,59, and 60, further, Domenico discloses the straps are integrally formed with device (see fig 2 and 4) as required by claims 50,52 and 54. At the time of the invention, it would have been an obvious to one skilled in art to have to make the device of Burgess and Holden to have straps having adhesive, as taught by of Domenico to have adhesive on top surface of the device to adhere the support device to the bottom of the foot and to secure the device better to sole of the foot.

4. With respect to claims 44,56, and 60, the limitations of "restricting extension and stretching of the outer skin tissue on the sole of the foot", when the device described above adheres to sole, it will obviously restrict extension of the skin and such that the tension forces applied to the plantar fascia from the forces on an arch of the foot which push the bones of the foot downwardly, and are able to reduce tension in the plantar fascia (0027), when the device of Burgess is secured to the sole of the user's foot which will result in treating pain in at least one of the heel, or arch or ball of the foot (see paragraph 0016 and 0027) and controls the step to prevent extension and stretching, reduce tension on the plantar fascia of the foot.

5. Claims 45, 72, 75-76, 78 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess and Holden in view of Desnoyers (3,482,683).
Burgess and Holden substantially disclose the invention as claimed; see rejection to claims 44, 62, 66 and 70-71 above; however, Burgess and Holden does not disclose that the sole member has a ratio of elongation (%) to tensile strength (ib/in-width) that is less than 0.9, whereby providing a balanced combination of strength and resistance to elongation.
However, Desnoyers teaches a pressure sensitive tape having material having ratio of elongation to tensile strength ratio of at least about 3 to 1 (column 3 lines 18-26, as broadly interprted as less than 0.9 because range of at least about in broadest term would meet required limitation). At the time of the invention was made, it would have been obvious to one having ordinary skill in the art to use the material to make the

device of Burgess and Holden to have tensile strength to ratio of elongation, as taught by Desnoyers to have resistance to tearing.

6. Claims 46 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess and Holden (465).

Burgess, and Holden substantially disclose the invention as claimed; see rejection to claim 45 above, further, Burgess and Holden discloses a device that has a uniform thickness (column 3 lines 52-54) of less than about 30 mils, (since column 3 lines 13-15, describes the thickness of about 1 mm to about 5 mm inherently discloses the less than about 30 mils required by claim, since examiner interprets “about” language as broadest reasonable interpretation, since 1 mils= 0.0254 mm) and formed of a fabric material (column 4 lines 5-10) Burgess further discloses a protective layer (150). However, Burgess and Holden do not disclose that device is 30 mils (0.762 mm) in thickness. At the time of the invention was made, it would have been obvious design choice to one having ordinary skill in the art to have thickness of 30 mils, since, such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

7. Claims 47, 61, 67 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess and Holden in view of Huddleston et al. (4,997,709).

Burgess and Holden substantially disclose the invention as claimed; see rejection to claims 44, 62, 66 and 70-71 above; Burgess and Holden does not disclose a support device that has less than 15% elongation when subjected to a tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759.

However, Huddleston et al. teaches novel adhesives and tapes having the tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759 (column 1 lines 48-63). At the time of the invention, it would have been an obvious to one skilled in art to use the tapes/adhesives of the tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759 to the device of Burgess and Holden, as taught by Huddleston et al. to have more resiliencies to the device.

8. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess, Holden and Huddleston et al.

Burgess, Holden and Huddleston et al substantially disclose the invention as claimed; see rejection to claims 44, 62, 66 and 70-71 above, further, Burgess discloses a device that has a uniform thickness (column 3 lines 52-54) of less than about 30 mils, (since column 3 lines 13-15, describes the thickness of about 1 mm to about 5 mm inherently discloses the less than about 30 mils required by claim, since examiner interprets “about” language as broadest reasonable interpretation, since 1 mils= 0.0254 mm) and formed of a fabric material (column 4 lines 5-10). However, Burgess, Holden and Huddleston et al does not discloses that device is 30 mils (0.762 mm) in thickness. At

the time of the invention was made, it would have been obvious design choice to one having ordinary skill in the art to have thickness of 30 mils, since, such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

9. Claims 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess, Holden and Desnoyers.

Burgess, Holden and Desnoyers substantially disclose the invention as claimed; see rejection to claims 44, 62, 66 and 70-71 above, further, Burgess discloses a device that has a uniform thickness (column 3 lines 52-54) of less than about 30 mils, (since column 3 lines 13-15, describes the thickness of about 1 mm to about 5 mm inherently discloses the less than about 30 mils required by claim, since examiner interprets "about" language as broadest reasonable interpretation, since 1 mils= 0.0254 mm) and formed of a fabric material (column 4 lines 5-10). However, Burgess, Holden and Desnoyers does not discloses that device is 30 mils (0.762 mm) in thickness. At the time of the invention was made, it would have been obvious design choice to one having ordinary skill in the art to have thickness of 30 mils, since, such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

10. Claims 77 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess, Holden and Desnoyers in view of Huddleston et al. (4,997,709). Burgess, Holden and Desnoyers substantially disclose the invention as claimed; see rejection to claims 75 and 78 above; Burgess, Holden and Desnoyers do not disclose a support device that has less than 15% elongation when subjected to a tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759.

However, Huddleston et al. teaches novel adhesives and tapes having the tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759 (column 1 lines 48-63). At the time of the invention, it would have been an obvious to one skilled in art to use the tapes/adhesives of the tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759 to the device of Burgess, Holden and Desnoyers, as taught by Huddleston et al. to have more resiliencies to the device.

Response to Arguments

11. Applicant's arguments filed 12/3/08 have been fully considered but they are not persuasive. After review of applicant's argument to 35 USC 112 rejections, the examiner withdrew the rejection to claims 44, 56, 62 and 66.

With respect to applicant's argument directed to the stretch resistance, please see rejection above. Applicant sets forth in the disclosure of the invention that "the stretch resistant device" is a sufficiently flexible article with adhesive lining and that has an

adhesive on the sole of the lining and that when the lining is adhered to the surface of a foot, the lining imparts at least some restriction to extension and stretching of the tissue. Similarly, the liner of Burgess, when applied to the sole of a foot, is applied via an adhesive on the liner and it is obvious that applying a liner with an adhesive, such as the Burgess device, to the bottom of the foot will provide some degree of restriction to the skin thus providing a means of prevention or restriction of extension and stretching of the tissue. Therefore, Burgess's liner is equivalent to the claimed support's "stretch resistant" property, since there are no other distinguishing structural elements that are claimed to provide this restriction of extension and stretching of the tissue. Further, it is again pointed out that this claim limitation of "stretch resistance" only requires the liner provide some degree of resistance to extension and stretching, and it is the position of the examiner that the device of Burgess meets this claimed limitation.

Also, applicant's own specification discloses his invention with the implication that it is only necessary to apply an adhesive to the sole of the foot to have some treating effect (see page 20 of applicant's original disclosure). The specification further teaches that additionally including straps and then connecting the straps is taught to be only an additional support.

Further, applicant does not disclose any specific type, amount, or degree of adhesive to have a therapeutic effect. If anything is adhered to the sole of a foot with it will impose some restriction of free motion of the sole of the foot and restrict some degree of stretching of the sole of the foot. Additionally, Burgess discloses that the adhesive can effectively bond the liner to the foot such that it is less likely to fall off

during normal activities (see column 4, lines 20-27 of applicant's original disclosure). Furthermore, Burgess discloses that their device conforms to the shape and contours of the sole of the foot and adjusts to flexing of the sole of the foot during walking or running without the adhesive tearing away from the foot (column 3 lines 40-51).

Lastly, no evidence has been provided by applicant to show that the adhesive layer of Burgess could not perform the restriction and resistance to stretching. It is the burden of applicant to provide convincing evidence against a prima facie case set forth by the examiner.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TARLA R. PATEL whose telephone number is (571)272-3143. The examiner can normally be reached on M-T 6-3.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tarla R Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772